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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,629	04/23/2001	Jason W. Trobaugh	13297.00019	3963

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EXAMINER
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EDWARDS, PATRICK L

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/840,629

Applicant(s)

TROBAUGH ET AL.

Examiner

Patrick L. Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23-33, 35-42 and 44-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-10, 13-15, 18-21, 24-30, 32, 33, 36-42, 44, 46, 47, 49 and 50 is/are allowed.
- 6) ☒ Claim(s) 1-4, 11, 12, 16, 17, 23, 31, 35, 45, 48 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The response received on 09-08-2005 has been placed in the file and was considered by the examiner. An action on the merits follows.

#### ***Response to Arguments***

2. The arguments filed on 09-08-2005 have been fully considered. A response to these arguments is provided below.

#### **Drawing Objections**

##### **Summary of Argument:**

Applicant has attached replacement drawing sheets and argues that the previous drawing objections are now overcome.

##### **Examiner's Response:**

The examiner agrees. The previous objections to the drawings are hereby withdrawn.

#### **Specification Objections**

##### **Summary of Argument:**

Applicant has amended the specification to refer to drawings 7-10.

##### **Examiner's Response:**

The previous objection to the specification is hereby withdrawn.

#### **Prior Art Rejections**

##### **Summary of Argument:**

(a) Applicant has amended claims 1, 45, and 48 to add the limitation of an image model including a data likelihood enabling a statistical inference to formulate underlying characteristics, where the data likelihood is constructed as a product of density functions characterizing each pixel. Applicant alleges that this added limitation puts the claim in condition for allowability. Specifically, applicant states that this added feature was found allowable in independent claim 5. (see remarks pg. 22). Applicant has similarly amended claims 2, 14, 18, 23, 35, and 47 to incorporate features from claim 5.

##### **Examiner's Response:**

(a) The examiner agrees that the added limitations come from an allowed claim. However, applicant is respectfully reminded that claim 5 was found allowable—not because of one single limitation—but rather because of the combination of claimed features. Accordingly, the amended claims will be considered on their own respective merits, and rejections will be provided below.

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*Allowable Subject Matter*

3. Claims 5-10, 13, 14-15, 18-21, 24-30, 32-33, 36-42, 44, 46-47 and 49-50 are allowed.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3 and 16, the phrase “the gross shape” lacks antecedent basis in the parent claim.

Claims 4 and 17 are rejected because of their respective dependencies

These claims cannot reasonably be reconciled with their parent claims because they describe characteristics of the “gross shape” and the respective parent claims make no mention of gross shape. Indeed, the applicant—via the instant amendment—has deleted from the independent claim the only limitation related to “gross shape.” Thus, it appears that the applicant does not intend to make reference to this feature. Since any interpretation of claims 3, 4, 16, or 17 would be in direct conflict with the parent claim and would further be purely speculative, such an interpretation can not be made pursuant to MPEP 2143.03.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 12, 16-17, 23, 31, 35, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheehan et al. (USPN 6,106,466).

As applied to claim 1—which is representative of claim 23—Sheehan discloses developing imaging system characteristics (see Fig. 11: Reference numeral 212 referring to a physics model of ultrasound reflection and attenuation in and around the heart (i.e. imaging system characteristics)).

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Sheehan further discloses developing microstructure (see Fig. 11: reference numeral 216 referring to a structural model of cardiac anatomy (i.e. microstructure)).

Sheehan further discloses incorporating the imaging system characteristics and the microstructure to form the image model (see Fig. 11: As can be seen in the figure, 210, 212, and 216 are incorporated to form the ultrasound imaging model).

Sheehan further discloses that the image model includes a data likelihood enabling a statistical inference to formulate underlying characteristics (see column 14, lines 22-26: The reference describes that the image model is based on a knowledge base of ventricular shapes defined by rotations, translations, and scaling of the set of training data (i.e. data likelihood) with the estimated covariance matrix for each of the vertices of the archetype shape (i.e. enabling a statistical inference)).

Sheehan further discloses that the data likelihood is constructed as a product of density functions characterizing each pixel (see col. 14 lines 22-26: the reference discloses a covariance matrix which is a product of density functions because it is defined with pixel values which are functions of the density of light at a give spot. The reference describes that the covariance gives the expected deviation from all the given pixel locations (i.e. product of density functions)).

As applied to claim 2—which is representative of claim 31—Sheehan discloses that the density function characterizing each pixel is assigned to each pixel based upon a classification of each pixel determined by a ratio of an amplitude mean value and a standard deviation value (Sheehan col. 14 lines 57-63: As was touched on in the above rejection to claim 1, Sheehan discloses that the pixels are characterized based upon a mean image and an expected deviation (i.e. standard deviation)).

Regarding claims 3-4 and 16-17, these limitations are inconsistent with the parent claim and therefore can not be said to limit that claim. This is discussed in the 112(2) rejection above. Accordingly, these claims are also anticipated by Sheehan.

As applied to claim 12, Sheehan et al. disclose that tissue is characterized by a reflectivity function (see column 10, lines 8-15: The reference describes that the epicardial surface of the heart (i.e. tissue) can be characterized by the reflected intensity of a sound wave (i.e. reflectivity function) as provided for in equation (5)).

With regard to claim 51, Sheehan further discloses that the gross shape is described by a volume of space (sheehan col. 1 line 66 – col. 2 line 2, and elsewhere throughout the specification).

With regard to claim 52, Sheehan fails to explicitly recite that the acoustic properties of the volume of space are represented by multiple discrete scatterers distributed across the volume. However, this limitation is inherent in the Sheehan disclosure as it is well established in the field of ultrasonic imaging that any object to be imaged is comprised of discrete targets which are distributed across the volume of the object. These discrete cell targets, which are found in tissue, for example, are commonly referred to as “scatterers.”

With regard to claim 54, Sheehan discloses estimating the shape of an object (sheehan col. 14 line 39).

Regarding claims 35 and 48, Sheehan further discloses a computer readable medium for performing the method (see generally, Sheehan).

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan et al. (U.S. Patent No. 6,106,466 A) and Seyed-Bolorforosh (U.S. Patent No. 5,841,889 A). The arguments as to the relevance of Sheehan et al. in the rejection of claim 1 above are incorporated herein.

Claim 11 calls for the imaging system characteristics to be described by a point spread function.

This element is absent from Sheehan et al.; however, Seyed-Bolorforosh, in the same field of endeavor of image processing and the same problem solving area of ultrasound imaging discloses such a feature (see column 3, lines 46-50: The reference describes the use of a three-dimensional point spread function.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Sheehan et al. by describing the imaging system characteristics using a three-dimensional point spread function as taught in Seyed-Bolorforosh because the use of such a three-dimensional point spread function gives the system the "ability to distinguish between different tissue types in a clinical ultrasound image" (see Seyed-Bolorforosh: column 3, lines 59-60).

10. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan as applied to claim 1 above, and further in view of Slayton et al. (USPN 6050943). The arguments as to the relevance of the aforesaid combination as applied above are incorporated herein.

Claim 53 adds the feature of an image model being used to estimate the the temperature of an object. Sheehan is silent with respect to temperature estimations. Slayton, however, discloses an ultrasonic transducer system that provides imaging capabilities and temperature estimation capabilities (see Slayton abstract). It would have been obvious to one reasonably skilled in the art at the time of the invention to augment Sheehan's method for image modeling by adding temperature estimation capabilities as taught by Slayton. Such a modification would have allowed for a more robust system capable of developing image models of objects and also estimating the temperature of those objects.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan et al. (USPN 6,106,466) and Seyed-Bolorforosh (USPN 5,841,889) (herein 'Seyed').

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With regard to claim 1, Sheehan et al. disclose a method for forming an image model, comprising the steps of: a. developing imaging system characteristics (see Sheehan Fig. 11: Reference numeral 212 referring to a physics model of ultrasound reflection and attenuation in and around heart (i.e. imaging system characteristics).); b. developing gross shape (see Sheehan Fig. 11: Reference numeral 210 referring archetype shape (i.e. gross shape).); c. developing microstructure (see Sheehan Fig. 11: Reference numeral 216 referring to structural model of cardiac anatomy (i.e. microstructure).); d. incorporating the imaging system characteristics, the gross shape and the microstructure to form the image model (see Sheehan Fig. 11: As can be seen in the figure, 210, 212, and 216 are incorporated to form the ultrasound imaging model.).

Further referring to claim 1, the above paragraph aptly states that Sheehan teaches the limitation of developing microstructure. The amended claim, however, requires developing sub-wavelength microstructure. This limitation is not expressly disclosed in Sheehan. Seyed, also in the field of ultrasound image processing, discloses developing sub-wavelength microstructure (Seyed col. 3 lines 45-50: The reference discloses developing microstructure (i.e. the texture of the tissue, which determines the type of tissue) which is small compared to wavelength (i.e. sub-wavelength). The 'reflectors' disclosed in the cited passage is simply referring to the tissue that the sound waves are reflecting off of (see col. 4 lines 15-16).).

It would have been obvious to one reasonably skilled in the art at the time of the invention to determine Sheehan's smoothness parameters (sheehan col. 14 line 45) as a sub-wavelength microstructure as taught by Seyed. Such a modification would have allowed for the ability to distinguish between different tissue types This would have been a very desirable result, because "The ability to distinguish between tissue types in a clinical ultrasound image is very important for the detection of diseased tissue" (see Seyed col. 3 lines 59-61).

### *Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (571) 272-7390. The examiner can normally be reached on 8:30am - 5:00pm M-F.

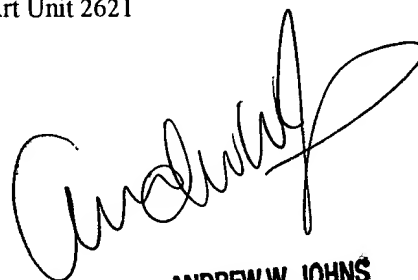
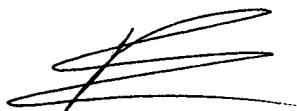
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Mancuso can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick L Edwards

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**ANDREW W. JOHNS**  
**PRIMARY EXAMINER**